

REMARKS

The Final Office Action of July 17, 2008, has been received and reviewed. Please amend the claims as previously set forth in conjunction with the contemporaneously filed Request for Continued Examination. New claims 65-68 are presented herein. Basis for new claims 65-68 can be found throughout the Specification and more specifically ¶¶ 11, 33, 35, 37, 39, 42, and 43 of the Specification as published and the claims as originally filed. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 21-31 and 43-63 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant notes that claims 27, 28, and 43-63 have been cancelled herein, rendering the rejection of those claims moot. Applicant respectfully traverses the remaining rejections as hereinafter set forth.

Claim 21

The Office asserts, at page 2 of the Final Office Action, that claim 21 is confusing in the recitation of “a means for encoding an inactive *Lactococcus* thymidylate synthase.” Although the applicant does not agree that any of the claims are indefinite, to expedite prosecution, claim 21 has been amended herein. Specifically, claim 21 has been amended to no longer recite “a means for encoding an inactive *Lactococcus* thymidylate synthase.” Consequently, applicant respectfully submits that claim 21 and the claims dependent therefrom can no longer be considered indefinite for the recitation of the phrase at issue.

Claim 22

The Office asserts that claim 22 is confusing for the recitation of “strain of *Lactococcus* bacterium comprises a thymidylate synthase gene selected from the group consisting of SEQ ID

NO:3 and SEQ ID NO:5” as the Specification teaches that SEQ ID NO:5 is a mutant version of SEQ ID NO:3. *Id.*

Applicant respectfully submits that one of ordinary skill in the art would not find the cited recitation confusing as it is clear from the claim and the Specification that both SEQ ID NO:5 and SEQ ID NO:3 both encode a thymidylate synthase. Even though SEQ ID NO:5 is a mutant version of SEQ ID NO:3, both sequences encode an active thymidylate synthase (*see, e.g.*, Specification as published at ¶ 40). Consequently, applicant submits that the cited recitation is not confusing to one of ordinary skill in the art.

Claim 31

The Office asserts that claim 31 is confusing in the recitation of “wherein said nucleic acid encoding an inactive *Lactococcus* thymidylate synthase comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:5” as at least SEQ ID NO:3 encodes an active *thyA*. Final Office Action at page 3. Although the applicant does not agree that any of the claims are indefinite, to expedite prosecution, claim 31 has been amended herein. Specifically, claim 31 has been amended to recite “an active *Lactococcus* thymidylate synthase.” Consequently, applicant submits that claim 31 can no longer be considered indefinite for the recitation of “an inactive *Lactococcus* thymidylate synthase.”

In view of at least the foregoing, applicant respectfully request the withdrawal of the rejections of claims 21-26 and 29-31 under 35 U.S.C. § 112, second paragraph, and reconsideration of same.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-10, 12-17, 21, 23-30, 32, and 34-64 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Nilsson *et al.* (WO 00/01799) (hereinafter “Nilsson”). Specifically, it was asserted that the *thyA* gene disclosed therein is chromosomally inactivated and comprises at least 1000 contiguous nucleotides that are at least 90% identical to a region of SEQ ID NOs: 1 and 2, where a region is construed by the Office to mean any two nucleotides.

Final Office Action at page 4. Applicant note that claims 4, 8, 9, 16, 27, 28, 36, 40, 41, and 43-64 are cancelled herein, rendering the rejections of those claims moot. Applicant respectfully traverses the rejections as hereinafter set forth.

Applicant notes that a claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicant respectfully asserts that claims 1-3, 5-7, 10, 12-15, 17, 21, 23-26, 29, 30, 32, 34, 35, 37-39, and 42 cannot be anticipated by Nilsson as Nilsson does not teach each and every element of these claims.

Specifically, Nilsson does not teach “a gene encoding a heterologous prophylactic or therapeutic molecule” as recited in amended claims 1, 21, and 32. Basis for the amendments to claims 1, 21, and 32 can be found throughout the Specification and more specifically in ¶¶ 11, 33, 35, 37, 39, 42, and 43 of the Specification as published of the application as published. Consequently, Nilsson cannot anticipate claims 1, 21, and 32.

Further, applicant has amended claim 1 to no longer recite “a region” which the Office has interpreted as two or more nucleotides. Consequently, with respect to claim 1 and the claims dependent therefrom, Nilsson can no longer be considered to read on these claims for having a region of 2 or more nucleotides that are at least 90% identical to SEQ ID NO:1 or SEQ ID NO:2.

Moreover, one of ordinary skill in the art would not be motivated to modify Nilsson to arrive at the present claims. The structural feature of “a gene encoding a heterologous prophylactic or therapeutic molecule,” as recited in amended claims 1, 21, and 32, clearly specifies the purpose that is central to the invention, *i.e.*, biological containment upon therapeutic deliver by *Lactococcus*. This purpose is completely different from that of Nilsson, who aimed to achieve resistance to bacteriophages (*see* Nilsson at page 1, lines 8-10 and page 4, lines 10-13).

More Specifically, Nilsson is clearly non-analogous art since it is in a field (bacteriophage resistance) which is not related to applicant’s invention (biological containment upon therapeutic delivery by *Lactococcus*), and would not have been consulted by a skilled person active in the field of bacterial therapeutic delivery. In addition, one would not have had any expectation of success that the *thyA* deficient *Lactococcus* of Nilsson would be capable of *in vivo* delivery of

therapeutic molecules. Indeed, there is no teaching in Nilsson that the *thyA* mutant of *Lactococcus* would be able to produce therapeutic molecules de novo in the thymine and thymidine poor environment upon delivery. Therefore, one of ordinary skill in the art would not alter the *Lactococcus* of Nilsson to include a gene encoding a heterologous prophylactic or therapeutic molecule.

In view of at least the foregoing, applicant respectfully requests the withdrawal of the rejections of claims 1, 21, and 32 under 35 U.S.C. § 102(b).

In addition, applicant respectfully submits that Nilsson cannot anticipate claims 2, 3, 5-7, 10, 12-15, 17, 23-26, 29, 30, 34, 35, 37-39, and 42, *inter alia*, as each of these claims depends, directly or indirectly, or from one of non-anticipated claims 1, 21, and 32 or incorporates all of the elements of one of these claims. Consequently, applicant respectfully requests the withdrawal of the rejections of claims 2, 3, 5-7, 10, 12-15, 17, 23-26, 29, 30, 34, 35, 37-39, and 42 under 35 U.S.C. § 102(b) and reconsideration of same.

CONCLUSION

In light of the above amendments and remarks, applicant respectfully requests reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Daniel J. Morath', with a stylized flourish at the end.

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